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EXAMINER	
CROW, ROBERT THOMAS	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL K. WOLBER and ERIC M. LEPROUST

Appeal 2009-003458
Application 10/699,281
Technology Center 1600

Decided: February 12, 2010

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1-13 and 21-25, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a method of detecting the presence of depurination reaction products on a surface of an in situ produced nucleic acid array (claims 1-13) and a method of detecting the presence of a nucleic acid analyte in a sample (claims 21-25). Claim 1 is illustrative:

1. A method of detecting the presence of depurination reaction products on a surface of an in situ produced nucleic acid array, said method comprising:

(a) contacting an in situ produced nucleic acid array that includes at least one depurination probe feature having a depurination probe with a sample comprising a target nucleic acid that specifically binds to said depurination probe; and

(b) detecting the amount of resultant binding complexes of said depurination probe and said target nucleic acid in said depurination probe feature to determine the presence of depurination reaction products on said surface.

The Examiner relies on the following evidence:

McGall	U.S. 5,843,655	Dec. 1, 1998
Weng et al.	U.S. 6,691,042 B2	Feb. 10, 2004

The rejection presented by the Examiner follows:

Claims 1-13 and 21-25 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of McGall and Weng.

We reverse.

ISSUE

Have Appellants established error in the Examiner's prima facie case of obviousness?

FINDINGS OF FACT

FF 1. "McGall teaches a method of detecting the presence of depurination reaction products on a surface of an in situ produced nucleic acid array" (Ans. 3).

FF 2. McGalls' method comprises "the use of a substrate containing [labeled] oligonucleotide linkers having an active site for coupling of nucleotides" (App. Br. 14). The substrate is then exposed to a test condition which is to be "evaluated for its capacity to cause depurination" (App. Br. 14-15; *see also* Ans. 3). Any labeled probes that remain on the substrate after exposure to the test condition "can be quantitated so as to determine the extent of the depurination caused by the test conditions" (App. Br. 15; *see also* Ans. 3).

FF 3. The Examiner finds that McGall does not teach "hybridization as a test condition for determining depurination" (Ans. 4 and 8).

FF 4. Weng teaches "a method of detecting the presence of nucleic acids, namely, measuring expression levels of nucleic acids using microarrays" (*id.*).

FF 5. The Examiner finds that Weng also teaches the use of hybridization "as a test condition (column 4, lines 58-67)" (*id.*).

FF 6. Weng teaches

> In preferred embodiments, the generated expression profile A vs. B are further corrected for fluorophore bias. As described, supra, the two-color fluorescent hybridization process introduces bias into the profile analysis because each species of mRNA that is labeled with fluorophore has a bias in its measured color ratio due to interaction of the fluorescent labeling molecule (fluorophore) with either the reverse transcription of the mRNA or with the hybridization efficiency or both. Such a bias is also present in the generated expression

> profile A vs. B if samples under conditions A and B are labeled with different fluorophores.

(Weng, col. 4, l. 58 - col. 5, l. 1.)

PRINCIPLES OF LAW

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992).

"'[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, *there must be some articulated reasoning* with some rational underpinning to support the legal conclusion of obviousness.'" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988, (Fed. Cir. 2006) (emphasis added).

On appeal to this Board, Appellants must show that the Examiner has not sustained the required burden. *See Ex parte Yamaguchi*, 88 USPQ2d 1606, 1608 and 1614 (BPAI 2008) (precedential); *Ex parte Fu*, 89 USPQ2d 1115, 1118 and 1123 (BPAI 2008) (precedential).

ANALYSIS

Appellants contend that "[t]he Examiner acknowledges that McGall is deficient in that it fails to teach or suggest the use of a hybridization condition as a test condition for determining depurination" (App. Br. 14; *see also* Reply Br. 6 ("McGall fails to teach any method of measuring depurination which involves hybridization")). We agree (FF 3).

Nevertheless, the Examiner "relies upon Weng to remedy the deficiencies of McGall" (App. Br. 14). In this regard, the Examiner concludes that:

> Use of the hybridization test condition of Weng et al in the method of McGall is thus interpreted as outlined in the single exemplary embodiment: two ensembles of oligonucleotides in two areas of an array of McGall are both subjected to the same hybridization test condition of Weng et al. The ensemble in the first area is subjected to cleavage of depurination products. The amount of label at each site is detected and compared to determine the presence of depurination reaction products on the surface of the array. Thus, the resultant binding complexes of the uncleaved depurination probes with the target nucleic acid are compared to the cleaved binding complexes of the depurination probes with the target nucleic acid to determine the presence of depurination reaction products on the surface of the array.
>
> It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the depurination detection test conditions as taught by McGall using hybridization as a test condition as taught by Weng et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because the modification would have resulted in providing a method of controlling the quality of the microarray production process as explicitly taught by Weng et al (column 5, lines 29-32).

(Ans. 4 and 8-9.)

Appellants contend that in order "[t]o establish a *prima facie* case of obviousness, the prior art reference, or references when combined, must teach or suggest all the claim limitations" (App. Br. 14). We agree.

Appellants contend that Weng fails to remedy the deficiencies of McGall (App. Br. 17). We agree. The Examiner's statement of the rejection

fails to provide a rational and articulate explanation as to why a person of ordinary skill in this art would conclude that it would have been prima facie obvious to a person of ordinary skill in this art at the time the invention was made to have modified McGalls' depurination detection test conditions with the so-called "hybridization . . . test condition" taught by Weng at column 4, lines 58-67 (FF 5-6). Notwithstanding the Examiner's contention to the contrary (FF 5), we find no suggestion of a "test condition" related to depurination at column 4, lines 58-37 of Weng (FF 6; *see also* Reply Br. 6 ("Weng is entirely silent regarding measurement of depurination events")).

CONCLUSION OF LAW

Appellants established error in the Examiner's prima facie case of obviousness. The rejection of claims 1-13 and 21-25 under 35 U.S.C. § 103(a) as unpatentable over the combination of McGall and Weng is reversed.

REVERSED

cdc

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